Appl. No. 10//694,130
Atty.Docket No. 6373R2RD2
Amdt. Dated November 11, 2004
Reply to First Office Action Dated August 11, 2004
Customer Number 27752

REMARKS

Claims 1, 2 and 6 are amended to correct informalities pointed out by the Examiner. A period is added at the end of Claim 1. Claims 1 and 2 are amended to clarify that the recited percentages of the components are by weight of the composition. Support for this amendment may be found in the Specification at Page 9, lines 19-20 which state:

All percentages used herein are by weight of the dentifrice composition, unless otherwise specified.

Claim 6 is amended to minimize the space between the terms "stannous" and "ion".

Claim 10 is amended to delete the phrase " aqueous carriers which are" as suggested by the Examiner.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested. Applicants are appreciative of the Examiner's careful review and suggestions.

Claims 1 to 12 remain pending in the application.

Rejection Under 35 USC 112, Second Paragraph

The Office Action states that Claims 1-12 are rejected under 35 U.S.C. § 112, 2nd Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

It is respectfully submitted that the claims as amended are in full compliance of the requirements of 35 U.S.C. § 112, 2nd Paragraph.

The percentages of the components in Claims 1 and 2 are now recited as being by weight of the composition. The term "aqueous carriers" which is considered confusing and unnecessary has been deleted.

However, the Examiner's objection to the term "polyphosphate anion" as having no antecedent basis is respectfully traversed. It is submitted that the term "polyphosphates" encompasses polyphosphate salts, as would readily be understood by those of skill in the art. The term "polyphosphates" is a generic term and accepted nomenclature for compounds including salts and other derivatives of polyphosphoric acid such as esters. The present polyphosphates are specifically defined to be water soluble, which means that a salt such as

sodium polyphosphate would be ionized in solution into sodium ions and polyphosphate anions. In contrast to the Examiner's contention, it is not necessary for the polyphosphate to be hydrolyzed to produce polyphosphate anion. In fact, hydrolysis of the polyphosphate is specifically being avoided which might occur if the water content of the composition were not controlled. Thus, the compositions are formulated to have a water content of not more than about 20% by weight to minimize hydrolysis of the polyphosphate resulting in production of shorter chains such as pyrophosphate (n=2) or orthophosphate.

It is respectfully submitted that the term "polyphosphate anion" has proper antecedent basis in that "linear polyphosphates", in particular those that are water-soluble would be a source of polyphosphate anion. Therefore the rejection under 35 U.S.C. § 112, 2nd Paragraph should be withdrawn.

Claims Rejection Under 35 USC §103(a)

It is stated in the Office Action that Claims 1-12 are rejected under 35 USC §103(a) as being unpatentable over Gaffar et al. (US 4,627,977) in view of Crisanti et al. (US 4,902,497).

Applicants respectfully traverse the Examiner's rejection of the claims under 35 USC 103(a) and submit that Claims 1-12 are distinct and unobvious from the cited art.

Firstly, Applicants present a brief synopsis of the present invention. The present invention as claimed, relates to single-phase dentifrice compositions comprising as essential components a stannous ion source stannous ion source comprising a stannous salt other than stannous fluoride or stannous monofluorophosphate, a water soluble linear polyphosphate having an average chain length of from about 4 or more and a limited total water content of not more than about 20%. The compositions are formulated such that the efficacy of stannous in the dentifrice as anti-plaque and anti-gingivitis agent is not reduced by the presence of the polyphosphate. The polyphosphates reduce the staining that may be caused by stannous, provided the composition is formulated to have a relatively low water content of not more than 20% and the ratio of total moles of polyphosphate anion to total moles of stannous ion is from about 0.2:1 to about 5:1. Limiting the water content minimizes the

hydrolysis of the polyphosphate, which would reduce the availability of polyphosphate. Having the recited ratio of polyphosphate to stannous ensures that a sufficient amount of polyphosphate is available to provide the anti-staining benefit.

Gaffar et al. (US 4,627,977) discloses a method of inhibiting dental calculus comprising applying to teeth a calculus-inhibiting amount of a dentifrice composition having a pH of about 4.5 to about 9 containing, in an orally acceptable vehicle, approximately by weight,

(a) 0.1 to 7% of one or a mixture of linear molecularly dehydrated polyphosphate salts selected from the group consisting of water soluble alkali metal pyrophosphates, tripolyphosphates and hexametaphosphates,

(b) a dentally acceptable silica polishing material, and

(c) an amount of a fluorine ion source sufficient to supply 25 ppm to 2,000 ppm of fluoride ions, and

(d) 0.05% to 3% of a water-soluble alkali metal or ammonium synthetic anionic linear polymeric polycarboxylate salt having a molecular weight of about 1,000 to about 1,000,000,

said composition when so applied to teeth being effective to inhibit dental calculus. Fluorine ion sources include alkali metal and tin fluorides, such as sodium and stannous fluorides, sodium monofluorophosphate (MFP) and mixtures thereof.

There is no disclosure whatsoever in Gaffar relating to the use of stannous as antigingivitis and antiplaque agent. In fact, Gaffar's compositions would only have stannous if stannous fluoride were selected as the fluoride source. There is no disclosure to use a stannous salt to supply stannous ions much less to use a stannous salt other than stannous fluoride or stannous monofluorophosphate as contemplated in the present compositions. The present invention is also distinguished from the Gaffar, et al. reference by virtue of the lower water content of the dentifrice compositions of not more than 20%. Gaffar et al. exemplifies a dentifrice composition comprising a polyphosphate (Hexaphos), sodium fluoride, and 37.578% water. Still further, the present invention does not require the synthetic linear polycarboxylate required in the Gaffar, et al. formulations. Gaffar

recognizes that polyphosphates are subject to enzymatic hydrolysis and thus teaches the use of the combination of fluoride and polycarboxylate to inhibit such hydrolysis. There is no teaching whatsoever to limit the water content to not more than 20% to minimize the hydrolysis of the polyphosphate.

It is asserted that Gaffar teaches that "other anticalculus agents" may be incorporated in the composition and that it would have been obvious to use a stannous compound such as taught by the secondary reference Crisanti et al. as such "other anticalculus agent" in Gaffar's composition and thus arrive at the present invention. Crisanti indeed teaches the use of stannous compounds such as stannous chloride and stannous gluconate complexed with certain acids or alcohols as anticalculus agents and that the complexed stannous compound provides sustained levels over extended periods of time, and thus improved anticalculus activity. Thus, it is contended that this provides motivation to use Crisanti's anticalculus agent to modify Gaffar's composition.

Applicants respectfully submit that Crisanti provides no suggestion whatsoever to improve upon Gaffar's composition or the polyphosphate used by Gaffar as the anticalculus agent. Contrary to the Examiner's contention, no motivation is provided to combine Crisanti's complexed stannous compound with another anticalculus agent. In fact, there would be no need for another anticalculus agent given that Crisanti's complexed stannous compound provides sustained bioavailability and thus improved anticalculus activity.

It is respectfully submitted that combining Crisanti with Gaffar does not establish a *prima facie* case of obviousness because neither reference teaches or suggests all of the claim limitations. There is no specific teaching or suggestion in either Gaffar or Crisanti with respect to limiting the water content of the compositions to no more than 20% to avoid polyphosphate hydrolysis or that a molar ratio of polyphosphate anion to stannous ion of from about 0.2:1 to about 5:1 must be present. Therefore, the claimed invention is unobvious and the rejection should be withdrawn.

CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied reference. In view of the foregoing, reconsideration of this application, entry of the amendments presented, withdrawal of the claims rejection under 35 U.S.C. § 112, 2nd Paragraph and under 35 USC 103(a) and allowance of Claims 1 to 12 are respectfully requested.

Respectfully submitted,

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